

PATENT COOPERATION TREATY

12 JAN 2005

from the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Rule 71.1)

To:

GILL JENNINGS & EVERY
Broadgate House
7 Eldon Street
London EC2M 7LH
GRANDE BRETAGNE

Date of mailing
(day/month/year)

12.11.2004

Applicant's or agent's file reference
MJB07161WO

IMPORTANT NOTIFICATION

International application No.
PCT/GB 03/03139

International filing date (day/month/year)
18.07.2003

Priority date (day/month/year)
19.07.2002

Applicant
THE TECHNOLOGY PARTNERSHIP PLC

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:



European Patent Office - P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk - Pays Bas
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl
Fax: +31 70 340 - 3016

Authorized Officer

Micheli, M


Tel. +31 70 340-3606



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT (PCT Article 36 and Rule 70)

Applicant's or agent's file reference MJB07161WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/GB 03/03139	International filing date (day/month/year) 18.07.2003	Priority date (day/month/year) 19.07.2002	
International Patent Classification (IPC) or both national classification and IPC B65D83/14			
Applicant THE TECHNOLOGY PARTNERSHIP PLC			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>			
Date of submission of the demand 19.02.2004		Date of completion of this report 12.11.2004	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Fournier, J Telephone No. +31 70 340-1031	



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03139**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-9 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/GB 03/03139**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☒ paid additional fees under protest.
☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-9, 11-14
	No: Claims	1 2 10
Inventive step (IS)	Yes: Claims	3-9 11 13 14
	No: Claims	1 2 10 12
Industrial applicability (IA)	Yes: Claims	1-14
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Lack of unity of invention

This international application does not comply with the requirement of unity of invention (Rule 13.1, 13.2, 13.3) because it comprises two inventions, invention I (claims 1-12) and invention II (claims 13-14).

Invention I (claims 1-12) relates to a valve mechanism comprising a first and a second valve mechanism for use in an inhaler comprising a pressurised container and a metering chamber. Claim 12 relates to an inhaler mechanism incorporating a valve mechanism according to any of the claims 1-11, connected to a pressurised container.

Invention II (claims 13-14) relates to a method of manufacturing an inhaler according to claim 12.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-3052382

D2: US-A-2 974 453

2. **Examination: INVENTION I, claims 1-12:**

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

D1 discloses a valve mechanism suitable for use in an inhaler comprising a pressurised container and a metering chamber, the valve mechanism comprising: a first valve member (2) arranged to be positioned between the pressurised container and the metering chamber, the first valve member (2) being movable between a closed position in which the container is closed (see figure 1), and an open position in which the container is open to the metering chamber (see figure 2), the first valve member (2) being biased to remain in the first position by the pressure in the container and a return spring (8).

The valve mechanism further comprises a second valve member (5). The second valve member (5) is a discharge tube. The second valve member (5) is movable between a rest position in which the metering chamber is closed, see figure 1, a metering position in which the second valve member (5) actuates the opening of the first valve member (2) to enable a metered dose to be dispensed into the metering chamber, see figure 2, and an open position in which the metering chamber is open to allow medicament to be inhaled. This open position is a position of the movable discharge tube between figure 3 and figure 4. As soon as the second valve member (5) is released from the position shown in figure 3, and well before it reaches the position shown in fig 1 or fig 4, the dispensing function defined by the open position in claim 1: "the metering chamber is open to allow a medicament to be inhaled" is achieved.

As all the technical features of claim 1 are known from D1, the subject-matter of this claim is not new.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/03139

- 2.2 Dependent claims 2 and 10 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, see document D1, figures 1-4.
3. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 12 does not involve an inventive step in the sense of Article 33(3) PCT.
Incorporating a valve mechanism according to claim 1 to an inhaler is one of several possible uses of such a valve mechanism and therefore the subject-matter of claim 12 cannot be considered as involving an inventive step.
4. The combination of the features of dependent claims 3-9 and 11 is neither known from, nor rendered obvious by, the available prior art.
5. **Examination, INVENTION II, Claims 13 and 14:**
- 5.1 Claim 13:
Nearest prior art: D2
D2 discloses a method of pressure filling an aerosol container. It comprises the steps of:
providing a container (10) to be pressurised closed by a first valve (16, 17);
inserting a material into the container (10) through the first valve (16, 17);
pressuring the container with propellant through the first valve and
attaching a stem.
Problem:
In order to vary the volume dispensed, i.e the volume of the metering chamber, the concentration of the medicament supplied to the container has to be varied.
Solution:
Attaching a second valve to form the metering chamber after the inserting and pressuring steps. With this method, a number of different metering chamber volumes can be achieved using the same size container and first valve. The available prior art teaches away from this solution, by forming the metering chamber prior to the filling step. The subject-matter of claim 13 is therefore new (Article 33(2) PCT) and is considered as involving an inventive step (Article 33(3) PCT).
- 5.2 Claim 14 is dependent on claim 13 and as such also meet the requirements of the PCT with respect to novelty and inventive step.